REMARKS

By way of summary, Claims 1-29 were pending in this application prior to this response. In the outstanding Office Action, Claims 1, 2, 6-9, 15 and 23-25 were rejected under 35 U.S.C. §102(b) as being anticipated by Yarger (U.S. 5,360,414). Claims 3-5, 11-12, 16, 19, 22 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Breznock (U.S. 6,638,253). Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Cambron (U.S. 6,017,493). Claims 13, 14, 17, 18, 20, 21, 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Wakabayashi (U.S. 6,352,525). In this Amendment, Claims 1, 20 and 26 have been amended and Claims 6 and 23 have been canceled. Accordingly, Claims 1-5, 7-22 and 24-29 remain pending.

1. **Claim Amendments**

In this Amendment, Claims 1, 20 and 26 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

2. **Claims 1, 2, 6-9, 15 and 23-25 are not anticipated, and cannot be rendered obvious by Yarger**

In the outstanding Office Action, Claims 1, 2, 6-9, 15 and 23-25 were rejected under 35 U.S.C. §102(b) as being anticipated by Yarger (U.S. 5,360,414). Applicant respectfully disagrees with this rejection because Yarger does not disclose, teach, or suggest all the limitations of the referenced claims.

Yarger discloses a suction tube with holes connected to several channels along the length of the surface of the tube, where the proximal end of the tube is designed to be connected to a suction source. Yarger Abstract. Yarger describes the suction source as a vacuum source for sump action, and states that:

> "Typically, the vacuum source is a combination suction and drainage collection device. One example of such devices is a squeeze bulb, not shown,

which is collapsed by squeezing to create a suction in the tube assembly 40. As the squeeze bulb is filled, it expands until no further suction is present. At that point, the squeeze bulb may be conveniently emptied. The type of suction/collection device is not intended to constitute the present invention per se."

Yarger col. 7, ll. 40-48. Certain figures from the Yarger reference are reproduced for the convenience of the Examiner:

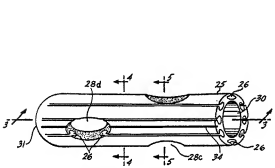

Fig. 2

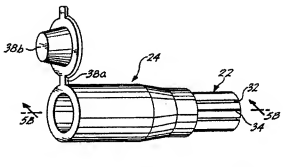

Fig. 5A.

Applicant respectfully submits that Yarger does not disclose, teach, or suggest the limitations recited at least in independent Claims 1, 15 and 20.

Claim 1 recites, among other things, a "first end adapted to connect to a vacuum source of at least approximately 50 torr." Applicant respectfully disagrees with Examiner's characterization of Yarger disclosing any vacuum source or system approximating 50 torr. As stated above, Yarger only contemplates a suction device such as a squeeze bulb, which is understood in the art to exert only a small suction pressure. Without reciting more, one skilled in the art could only conclude from Yarger that the disclosed device uses a low vacuum pressure. As stated in the Applicant's specification, "[e]xisting chest drainage systems conventionally use a low vacuum pressure. In such systems, the vacuum pressure applied to the chest tube is normally -20 cmH_2O (= 14.7 torr) or less. A dry unit with a pressure gauge may use higher pressure, but only slightly higher." Applicant specification at [0007]. The Applicant's specification goes on to state, "[e]xisting chest drainage systems use a conventional vacuum pressure of 14.7 torr. Presently, vacuum pressure in and around the range of 25-35 torr is considered to be 'high suction pressure.'" Applicant specification at [0022].

Claim 15 recites, among other things, a "high vacuum pressure body cavity drainage system, comprising ... a vacuum source of approximately 50 torr or greater." As discussed above, Yarger discloses no device for working with a vacuum source of approximately 50 torr or greater.

Amended Claims 1 and 15 further recite, among other things, that "each hole has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube." Amended Claims 1 and 15 include language taken from canceled Claim 6. With respect to canceled Claim 6 and amended Claims 1 and 15 Applicant respectfully disagrees with the Examiner's characterization that Yarger discloses holes in the tube wherein each "hole has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube (Col. 6, lines 14-19)." Office Action p. 2. At Col. 6, lines 14-19 Yarger states "In another design criteria, it is important that the diameter of the holes 28 is smaller than the inside diameter 30 of the tubular section 22 so that any debris that does enter the tubular section through the holes 28 will freely travel along the tubular section toward the proximal end thereof." Yarger simply discloses that the holes in the side of the Yarger tube should not be so large as to allow debris to pass through that hole to block the main lumen of the Yarger device. Yarger's requirement can be met with any side hole with an area equivalent to a diameter that is 90%, 95% or even 99.9% of the diameter of the Yarger tube regardless of how unsafe such hole areas would be in the presence of high vacuum. Yarger does not disclose Applicant's claimed diameter ratio for a safe, high-vacuum operated device.

Claim 20 recites, among other things, "a vacuum source of approximately 50 torr or greater," a "vacuum end of said connector adapted to receive a vacuum force" and "a vacuum chamber, said vacuum chamber having a gas outlet port coupled to said vacuum source, said vacuum chamber having an inlet port coupled to said vacuum end of said connector, said inlet port communicating a vacuum force from said gas outlet port to said vacuum end of said connector, said vacuum chamber having a fluid drainage outlet port through which fluid matter from said body cavity flows in a direction away from said body cavity." As discussed above, Yarger discloses no device for working with a vacuum source of approximately 50 torr or greater and does not disclose any vacuum chamber, much less any vacuum chamber claimed in Claim 20.

Amended Claim 20 further recites, among other things, "the largest area of any of said side holes is approximately that of a circle having a diameter of less than one half the internal diameter of said tube." Amended Claims 20 includes language taken from canceled Claim 23. With respect to canceled Claim 23 and amended Claim 20 Applicant respectfully disagrees with the Examiner characterization that Yarger discloses holes in the tube wherein each "hole has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube (Col. 6, lines 14-19)." Office Action p. 2. Despite the language of Claim 23 being different, Yarger is distinguishable for at least the following reasons. At Col. 6, lines 14-19 Yarger states "In another design criteria, it is important that the diameter of the holes 28 is smaller than the inside diameter 30 of the tubular section 22 so that any debris that does enter the tubular section through the holes 28 will freely travel along the tubular section toward the proximal end thereof." Again, as explained above Yarger does not disclose a specific diameter ratio for a safe, high-vacuum operated device as claimed by the Applicant, but rather expressly encourages unsafe holes areas with virtually the same or slightly smaller circular areas as the main lumen.

Thus, Applicant respectfully submits that Yarger fails to teach or suggest all the limitations of Claim 1, 15 or 20. Accordingly, Applicant respectfully requests that the rejection of Claims 1 and 15 under § 102 based on Yarger be withdrawn.

Claims 2, 7-9 and 24-25 depend from independent Claims 1, 15 and 20 and are allowable for the same reasons set forth above with respect to Claims 1, 15 and 20 in addition to the patentable subject matter contained therein. Accordingly, Applicant respectfully requests that the rejection of Claims 1, 2, 7-9, 15 and 24-25 under § 102(b) based on Yarger be withdrawn.

Further, with respect to Claim 7 Applicant respectfully disagrees with the Examiner characterization that Yarger discloses holes in the tube wherein each "hole has an area no greater than that of a circle having a diameter of around one half of an internal diameter of said tube (Col. 6, lines 14-19)." Office Action p. 2. As discussed above, at Col. 6, lines 14-19 Yarger states "In another design criteria, it is important that the diameter of the holes 28 is smaller than the inside diameter 30 of the tubular section 22 so that any debris that does enter the tubular section through the holes 28 will freely travel along the tubular section toward the proximal end

thereof." Yarger does not disclose a specific diameter ratio for a safe, high-vacuum operated device as claimed by the Applicant.

Furthermore, with respect to Claims 8-9 and 24-25 Applicant respectfully disagrees with the Examiner characterization that Yarger discloses a hole that has an area no greater than that of a circle having a diameter of 1 mm, or a hole that has an area no greater than that of a circle having a diameter of 0.5 mm at Col. 5, lines 2-7. Office Action p. 2-3. At Col. 5, lines 2-7 Yarger states: "In this regard, preferably the width of the entrance channels 32 may range from 0.1 mm to 1.0 mm, depending on the type of tissue and debris desired to be excluded, the overall diameter of the tube section, and also the volume of the wound to be drained."

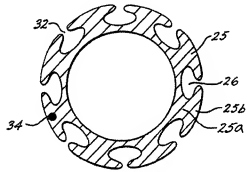

Fig. 4.

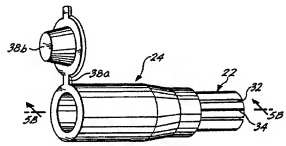

Fig. 5A.

As can be seen in Figs. 4 and 5 at reference numeral 32, Yarger is discussing the width of a channel that runs the length of the tube, not a hole diameter. The area defined by Yarger would far exceed the area claimed because the 0.1 mm to 1.0 mm width dimension would need to be multiplied by the entire length of the tube to correspond to the area of the channels. Accordingly, Applicant respectfully requests that the rejection of Claims 6-9 and 23-25 under § 102(b) based on Yarger be withdrawn.

3. **Claims 3-5, 11-12, 16, 19, 22 and 26-27 cannot be rendered obvious by Yarger in view of Breznock**

In the outstanding Office Action, Claims 3-5, 11-12, 16, 19, 22 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Breznock (U.S. 6,638,253). As discussed above, Yarger does not anticipate the claims of the present application. Dependent claims 3-5, 11-12, 16, 19, 22 and 26-27 depend from independent Claims 1, 15 and 20. For at least the reasons set forth above with respect to Claims 1, 15 and 20 Applicant

respectfully submit that Claims 3-5, 11-12, 16, 19, 22 and 26-27 are patentable over Yarger in view of Breznock. Claims 3-5, 11-12, 16, 19, 22 and 26-27 are also are patentable over Yarger in view of Breznock in view of the additional limitations recited in each of the claims. Further, Applicant respectfully disagrees with this rejection because the combination of Yarger and Breznock do not disclose, teach, or suggest all the limitations of the referenced claims.

Applicant respectfully disagrees with the Examiner characterization that Breznock discloses a vacuum source of approximately 100 torr or greater (citing Col. 4, lines 32-52 for Claim 3 and Col. 8, lines 28-37 for claims 19 and 22). Office Action p. 4. Within Col. 4, lines 32-52 Breznock states:

> "At least a portion of the tubing 22 is preferably stiffened with a helical winding of material such as stainless steel, nitinol and the like. The stiffening 30 could also be created using corrugations in the tubing 22 or by addition of a strong polymer such as glass-filled polycarbonate instead of the metal helical winding. The stiffening member 30 serves the purpose of preventing collapse of the cannula 10 when vacuum is applied to the drainage lumen 32."

The Examiner's cited paragraph does not disclose any particular vacuum levels, and instead illustrates aspects of Breznock teaching away from the Applicant's Claim 3. Breznock relies on the use of additional structure of helical winding materials to prevent collapse of the tube under even normal vacuum conditions, and does not present a solution for high vacuum tubes that do not use helical supports as is claimed in Claim 3. Regarding Claims 19 and 22, within Col. 8, lines 28-37 Breznock states: "The typical vacuum system is operated by an electrical vacuum pump and regulator to maintain a low level vacuum of 1 to 100 mm Hg. Preferably, the vacuum is maintained at a level of 1 to 20 mm Hg." Notably, "a vacuum source ... of approximately 100 torr or greater" is not within Breznock's preferred range up to 20 mm Hg.

With respect to Claim 5, Applicant respectfully disagrees with the Examiner characterization that Breznock discloses at least 100 holes relying on Fig. 1 and Col. 4, lines 64-67 and Col. 5, lines 1-5. Office Action p. 4. Fig. 1 from Breznock, reproduced below, does not show at least 100 holes in the wall, it shows about 18 holes.

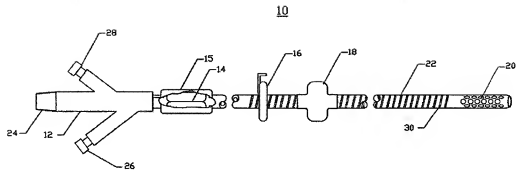

Figure 1

Breznock Col. 4, lines 64-67 and Col. 5, lines 1-5 state in relevant part, "The holes 20 are of sufficient size and quantity to allow for passage of fluid, thrombus and debris that might need to be removed from the chest cavity." This does not disclose over 100 holes. It merely states in general terms that there should be big enough holes and numerous enough holes to take debris from a chest cavity.

With regard to independent Claim 26, Applicant respectfully disagrees with Examiner's characterization that Col. 8, lines 28-37 in Breznock discloses "a means for regulating a respective suction force applied at each of a multiplicity of locations such that each of a respective suction forces is incapable of injuring bodily tissue exposed within a body cavity." Office Action p. 4. Breznock Col. 8, lines 28-37 discloses stopping a vacuum system to cause a valve 14 to close and seal a drainage lumen 32. Applicant asserts that this disclosure does not apply to a means for regulating a respective suction force applied at each of a multiplicity of locations such that each of a respective suction forces is incapable of injuring bodily tissue exposed within a body cavity.

Accordingly, for all the reasons discussed above, Applicant respectfully requests that the rejection of Claims 3-5, 11-12, 16, 19, 22 and 26-27 as being unpatentable over Yarger in view of Breznock be withdrawn.

4. **Claim 10 cannot be rendered obvious by Yarger in view of Cambron**

In the outstanding Office Action, Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Cambron (U.S. 6,017,493). As discussed above, Yarger does not anticipate the claims of the present application. Further, Applicant respectfully

disagrees with this rejection because the combination of Yarger and Cambron do not disclose, teach, or suggest all the limitations of the referenced claims.

Applicant asserts that one skilled in the art would not have found a reason to combine Yarger with Cambron, and that the Examiner has not explicitly articulated any reason why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant. Furthermore, the combination frustrates the intended purpose of the primary reference, rendering the device of the primary reference inoperable for its intended purpose.

The Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* refines the issue of obviousness under 35 U.S.C. §103(a) in relation to prior art. *KSR Int'l. v. Teleflex, Inc.,* No 04-1350 (U.S. Apr. 30, 2007). The Court noted that the analysis supporting a rejection under 35 U.S.C. §103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements: in the manner claimed. The Court specifically stated:

> Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**. *See In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

KSR, slip op. at 14 (emphasis added). Therefore, in making a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, Applicant submits that the Examiner must expressly identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Beyond the conclusory statements made in the Office Action, the Examiner has failed to do so.

Furthermore, one skilled in the art would not look to Cambron to modify the tube of Yarger, because in order to make the primary Yarger method and device operable the Yarger device uses a plurality of holes in the wall of the tube to remove debris. In contrast, Cambron discloses tables and statistics on catheter diameters for tubes vacuum assisted venous drainage reservoirs with only a single orifice at the distal tip of the Cambron tube. From the disclosure,

and even in the tables cited by the Examiner, a pressure measurement is taken at the distal orifice. The cited tables, reproduced below indicate a pressure measurement only at a reservoir end and a cannula end:

TABLE III

(Cannula Size = 20 Fr)

Head Height (inch)	Vacuum (mmHg)	Pump Flow (lpm)	Pressure Measurements @ Cannula End (mmHg)	Pressure Measurements @ Reservoir End (mmHg)
6	0	.83	-32	6
6	-15	1.19	-46	-11
6	-30	1.50	-59	-26
6	-45	1.75	-73	-45
6	-60	2.06	-86	-61
6	-75	2.30	-99	-77
12	0	1.20	-47	-3
12	-15	1.48	-57	-14
12	-30	1.79	-71	-30
12	-45	2.03	-84	-46
12	-60	2.31	-98	-63
12	-75	2.53	-111	-78
18	0	1.75	-41	7
18	-15	2.18	-55	-6
18	-30	2.56	-70	-19
18	-45	2.82	-82	-32
18	-60	3.15	-95	-44
18	-75	3.52	-109	-57

TABLE IV

(Cannula Size = 18 Fr)

Head Height (inch)	Vacuum (mmHg)	Pump Flow (lpm)	Pressure Measurements @ Cannula End (mmHg)	Pressure Measurements @ Reservoir End (mmHg)
6	0	.67	-34	3
6	-75	1.81	-104	-80
12	0	.89	-45	3
12	-15	1.13	-57	-11
12	-30	1.43	-72	-29
12	-45	1.67	-86	-45
12	-60	1.94	-102	-65
12	-75	2.12	-115	-80
18	0	1.00	-55	3
18	-15	1.22	-70	-16
18	-30	1.62	-84	-34
18	-45	1.79	-96	-47
18	-60	2.00	-112	-57
18	-75	2.17	-127	-85

Information that might be useful in vacuum tube applications with a single distal orifice does not apply to the structurally distinct characteristics of a vacuum tube with a plurality of holes along its walls.

Further, the combination frustrates the intended purpose of the primary reference, rendering the device of the primary reference inoperable for its intended purpose. A single orifice would not dissipate the suction on surrounding tissue through the set of parallel channels as disclosed in Yarger, putting the patient at serious risk of internal tissue damage.

Therefore, even if the Examiner could expressly identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed, the combination frustrates the intended purpose of the primary reference, rendering the device of the primary reference inoperable for its intended purpose. Furthermore, even if the references were combined, Yarger and Cambron fail to produce the claimed embodiment of Applicant's invention because Yarger and Cambron, alone or in combination, fail to disclose a device as claimed in Claim 10. Accordingly, for all the reasons discussed above, Applicant respectfully

requests that the rejection of Claim 10 as being unpatentable over Yarger in view of Cambron be withdrawn.

5. **Claims 13, 14, 17, 18, 20, 21, 28 and 29 cannot be rendered obvious by Yarger in view of Wakabayashi**

In the outstanding Office Action, Claims 13, 14, 17, 18, 20, 21, 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Wakabayashi (U.S. 6,352,525). As discussed above, Yarger does not anticipate the claims of the present application. Independent Claim 20 has been discussed with respect to Yarger above. Claims 13, 14, 17, 18 and 21 depend from independent Claims 1, 15 and 20. Applicant respectfully submits that Claims 13, 14, 17, 18 and 21 are patentable over Yarger in view of Wakabayashi. Claims 13, 14, 17, 18 and 21 are also are patentable over Yarger in view of Wakabayashi in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 13, 14, 17, 18 and 21 based on Yarger in view of Wakabayashi.

6. **Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or prior art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution.

Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, he is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 8-31-07

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